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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,515	02/24/2000	Kiron M Das	UMD-1.0-042	5568

22249 7590 05/13/2002

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EXAMINER
BRUMBACK, BRENDA G

ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 05/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/512,515	DAS, KIRON M	
	Examiner	Art Unit	
	Brenda G. Brumback	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *21-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is responsive to the amendment filed 02/25/2002. Claims 1-3, 6-7, 9-13, 16, 19, and 20 were amended. Claims 1-29 are pending.

This application contains claims 21-29 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-20 are under examination on the merits.

Information Disclosure Statement

The Information Disclosure Statement filed 02/25/2002 has been considered. A signed copy of the form PTO-1449 is attached hereto.

Specification

The objection to the specification for the incorrect address of the ATCC is withdrawn due to applicant's amendment thereof.

Claim Objections

The objection to claim 2 for the misspelling of "epithelial" is withdrawn pursuant to applicant's amendment thereof.

Claim Rejections - 35 USC § 112

The rejections of claims 3, 6, 7, 11, 13, 16, 17, and 20 under 35 U.S.C. 112, second paragraph, for the indirectly attached label, for insufficient antecedent basis, and for the syntax of claim 11 are withdrawn pursuant to applicant's amendment thereof.

The rejection of claims 9 and 19 under 35 U.S.C. 112, second paragraph, is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that persons skilled in the art would understand that the negative control assay is to be performed on cells that do not contain the human gastric intestinal metaplasia antigen; however, the claim remains indefinite because they recite that the negative control assay is performed on a negative control sample in order to detect cells of human colonic type gastric intestinal metaplasia. Such cells would inherently contain human gastric intestinal metaplasia antigen. The claims further recite that the presence of human colonic type gastric intestinal metaplasia cells in the test tissue "above" the presence of the cells in the negative control indicates a positive diagnosis. Applicant's claims would seem to indicate that colonic type gastric intestinal metaplasia positive cells can be present in the negative control sample, albeit at a lower level than in a gastric tissue sample considered to be positive. It thus remains unclear how a sample in which positive cells are present can be considered to be a "negative control sample" because the art recognized definition of a negative control sample is one which is negative by the assay in question. Correction is required.

The rejection of claims 1-20 under 35 U.S.C. 112, first paragraph, for the scope of enablement is withdrawn pursuant to applicant's amendments limiting the claimed method to diagnosis of human gastric intestinal metaplasia of the colonic type.

The rejection of claims 6-8 and 16-20 under 35 U.S.C. 112, first paragraph, for intestinal tissue, is withdrawn pursuant to applicant's amendment thereof to recite gastric tissue.

The rejection of claim 1-20 under 35 U.S.C. 112, first paragraph, for the deposit requirement is withdrawn subsequent to the Das Declaration.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1, 3-5, 9-11, and 13-15 under 35 U.S.C. 102(b) as anticipated by Garewal et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that Garewal et al. does not anticipate the claimed method because the gastric cardia biopsies of Garewal et al. were from esophageal tissue taken from the opening of the esophagus into the stomach, while the colonic gastric intestinal metaplasia of the present invention involves gastric tissue that is histologically different from the tissue used in Garewal et al. Applicant's argument is not persuasive because Garewal et al. teaches performing the method using normal gastric cardia (negative control) and gastric cardia biopsies showing gastric intestinal metaplasia. Stedman's Medical Dictionary (27^{th} ed.) defines gastric as "relating to the stomach" and defines "cardia" as the area of the stomach close to the esophageal opening. Thus, the gastric cardia biopsies used in Garewal et al. are by definition stomach tissues encompassed within the gastric tissue samples of the present invention. Applicant has provided no evidence that gastric cardia is not considered to be a subset of gastric tissue, but rather is taught in the art to be histologically distinct from gastric tissue. Absent such evidence, Garewal et al. anticipates the claimed invention. Argument in the absence of evidence is not persuasive.

Applicant further argues that the present invention requires reactivity of the DAS-1 antibody with the human intestinal metaplasia antigen, while the Garewal et al. reference neither mentions nor describes such a limitation. Garewal, however, teaches contacting gastric tissue with the same monoclonal antibody as that of the present invention. Applicant's claim merely recites a newly discovered property of the prior art antibody. The claiming of a new property which is inherently present in the prior art does not make a claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

The rejection of claims 1-5 and 9-15 under 35 U.S.C. 102(a) as anticipated by Griffel et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that Griffel et al. did not show that DAS-1 could react with gastric metaplastic tissue and that this could be diagnostic for the risk of gastric carcinoma. However, Griffel et al. specifically state the following at page 41, first full paragraph:

"... MAbDAS-1 has been shown to react with only approximately 25% of cases of gastric intestinal metaplasia (25), which is approximately the percentage that is thought to be of the incomplete or colonic type (26). This suggests that this antibody does not react with all intestinal metaplasia, but only that of the colonic type".

Since applicant's claimed method is directed to diagnosis of human colonic type gastric intestinal metaplasia by contacting a gastric tissue sample with MAbDAS-1, Griffel et al. anticipate the claimed method. The fact that Griffel et al. teach that the monoclonal antibody can also be used to distinguish the terminal stage of progression of tissue to Barrett's Esophagus does not negate the teaching that reactivity of gastric tissue with the monoclonal antibody is diagnostic for of human colonic type gastric intestinal metaplasia. Applicant's argument regarding the gastric tissues of the present invention and the prior art has been addressed *supra*.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 2 and 12 under 35 U.S.C. 103(a) as unpatentable over Garewal et al. in view of Badve et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant's argument that the tissue tested in the prior art is histologically different from the tissue of the present invention has been addressed *supra.*

Applicant further argues that one of skill in the art would not have had a reasonable expectation of success because the prior art teaches away from the notion that DAS-1 would be reactive with gastric tissue and predictive of gastric cancer. This argument has been considered to the extent possible without the cited Das references, as no copies were provided with applicant's response. However, the art clearly points directly to the claimed invention and teaches an expectation of success in using DAS-1 for diagnosis of colonic type gastric intestinal metaplasia as follows. Garewal teaches that DAS-1 reacts with the subset of incomplete gastric intestinal metaplasia. Badve et al. teach that DAS-1 recognizes a protein unique to colonic epithelium. The art teaches that incomplete gastric intestinal metaplasia is synonymous with colonic type gastric intestinal metaplasia (see Griffel et al., page 41, first partial paragraph, last sentence). Thus, the art points directly to and teaches a reasonable expectation of success using DAS-1 to diagnose colonic type gastric intestinal metaplasia. The teaching that DAS-1 does not react with normal tissue of the small intestine or with squamous cell carcinoma does not teach away from an expectation of success using DAS-1 for diagnosis of colonic type gastric intestinal metaplasia, but rather would seem to buttress it by teaching that the antibody is specifically reactive only with cells possessing the colonic protein.

The rejection of claims 1-6, 8-16, and 18-20 under 35 U.S.C. 103(a) as unpatentable over either Garewal et al. in view of Badve et al., or Griffel et al., as applied to claims 1-5 and 9-15 above, and further in view of Pantuck et al., Babaev et al., and Petersen et al. is maintained.

The rejection of claims 7 and 17 under 35 U.S.C. 103(a) as unpatentable over either of Garewal et al. in view of Badve et al., or Griffel et al., in view of Pantuck et al., Badve et al., and Petersen et al. as applied to claims 1-6, 8-16, and 18-20 above and further in view of Pinkus et al. is maintained.

Applicant's arguments regarding the tissues of the present invention compared to those of the prior art and whether the prior art teaches toward or away from the present invention have both been previously addressed. No additional arguments were presented pertaining to the present grounds of rejection.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner cannot be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback
Patent Examiner